K113377

GRIFOLS

Grifols USA, Inc.
2410 Lillyvale Avenue
Los Angeles, CA
90032-3548
Tel. (323) 225-2221
(800) 421-0008
www.grifols.com

510(k) Summary

DEC 14 2012

1. **Date 510(k) Summary Prepared:** 12 December 2012

2. **510(k) Owner:** Grifols USA, LLC

3. **Submitter:** Grifols USA, LLC

Submitter Name: Grifols USA, LLC.
Contact Person: Catherine L. Wong
Address: 2410 Lillyvale Avenue
Los Angeles, CA 90032-3514
Telephone: (323) 227-7280
Fax No.: (323) 441-7902

4. **Device Information**

Proprietary and Established Names: α-Gliatest® IgA, α-Gliatest®IgG, α-GliaPep® IgA, and α-GliaPep®IgG

Common Names: Gliadin IgA and Gliadin IgG

5. **Regulatory Information:**

Regulation No.: 21 CFR § 866.5750
Regulation Section: Radioallergosorbent (RAST) immunological test system
Classification: Class 2
Product Code: MST, Antibodies, Gliadin
Panel: Immunology

6. **Predicate Devices:**
Aeskulisa® Glia A (K052439), predicate for α-Gliatest® IgA and α-GliaPep® IgA
Aeskulisa® Glia G (K052439), predicate for α-Gliatest® IgG and α-GliaPep® IgG

7. Device Description

Each test kit for α-Gliatest® IgA, α-Gliatest® IgG, α-GliaPep® IgA, and α-GliaPep® IgG consists of one (1) microtiter plate (12 strips of 8 microwells coated with purified α-gliadin antigen or deamidated gliadin peptide antigen), assay controls (positive and negative), a ready-to-use set of five (5) calibrators, Horseradish Peroxidase (HRP) goat anti-human IgA or IgG conjugate, serum diluent, Tetramethylbenzidine (TMB) enzyme substrate, stop solution, and washing solution required for the assay.

8. Intended Use

- Intended Use for **α-Gliatest® IgA**:

  The α-Gliatest® IgA is intended for the semi-quantitative determination of IgA antibodies directed against gliadin in human serum. The assay is an aid in the diagnosis of celiac disease and should be used in conjunction with other serological tests and clinical findings.

- Intended Use for **α-Gliatest® IgG**:

  The α-Gliatest® IgG is intended for the semi-quantitative determination of IgG antibodies directed against gliadin in human serum. The assay is an aid in the diagnosis of celiac disease and should be used in conjunction with other serological tests and clinical findings.

- Intended Use for **α-GliaPep® IgA**:

  The α-GliaPep® IgA is intended for the semi-quantitative determination of IgA antibodies directed against deamidated gliadin peptide in human serum. The assay is an aid in the diagnosis of celiac disease and should be used in conjunction with other serological tests and clinical findings.

- Intended Use for **α-GliaPep® IgG**:

  The α-GliaPep® IgG is intended for the semi-quantitative determination of IgG antibodies directed against deamidated gliadin peptide in human serum. The assay is an aid in the diagnosis of celiac disease and should be used in conjunction with other serological tests and clinical findings.

9. Summary of Comparison with Predicate Device

The devices, α-Gliatest® IgA, α-Gliatest® IgG, α-GliaPep® IgA, and α-GliaPep® IgG, have been compared with their predicate devices (Aeskulisa® Glia A and Aeskulisa® Glia G, K052439), and found to be substantially equivalent.

The design, features, technological characteristics, specifications and performance of the devices have been compared with those of the predicate devices, as shown in Tables 1, 2, 3 and 4.

Table 1 Device Similarities Between α-Gliatest® IgA, α-GliaPep® IgA and Predicate (Aeskulisa® Glia A, K052439)

No.	Item	α-Gliatest® IgA	α-GliaPep® IgA	Predicate AESKULISA® Glia-A (K052439)
1.	Intended Use	The α-Gliatest® IgA is intended for the semi-quantitative determination of IgA antibodies directed against gliadin in human serum. The assay is an aid in the diagnosis of celiac disease and should be used in conjunction with other serological tests and clinical findings.	The α-GliaPep® IgA is intended for the semi-quantitative determination of IgA antibodies directed against deamidated gliadin peptide in human serum. The assay is an aid in the diagnosis of celiac disease and should be used in conjunction with other serological tests and clinical findings.	The AESKULISA Glia-A is a solid phase enzyme immunoassay for the semi-quantitative and qualitative detection of IgA antibodies against gliadin in human serum. The assay is an aid in the diagnosis of celiac disease (gluten-sensitive enteropathy) and should be used in conjunction with other serological tests and clinical findings.
2.	Methodology	ELISA	Same	Same
3.	Analyte	IgA antibodies against gliadin in human serum	IgA antibodies against deamidated gliadin peptide in human serum	IgA antibodies against gliadin in human serum
4.	Enzyme-Conjugate	Horseradish peroxidase	Same	Same
5.	Substrate/ Chromogen	TMB	Same	Same
6.	OD Reading	450 nm	Same	Same
7.	Positive Control	Human serum	Same	Same
8.	Negative Control	Human serum	Same	Same
9.	Storage	2-8°C	Same	Same
10.	Patient Sample Dilution	1:101	Same	Same
11.	Patient Sample Volume Required	100 µL	Same	Same

Table 2 Device Differences Between α-Gliatest® IgA, α-GliaPep® IgA and Predicate (Aeskulisa® Glia A, K052439)

No.	Item	α-Gliatest® IgA	α-GliaPep® IgA	Predicate AESKULISA® Glia-A (K052439)
1.	Capture Antigen	Purified α-gliadin antigen	Deamidated gliadin peptide	Purified α-gliadin antigen
2.	Controls	Positive, Negative Controls	Positive, Negative Controls	Positive, Negative, and Cut-off Controls
3.	Calibrators	5 Levels: 0, 10, 20, 50, 100 AU/mL	5 Levels: 0, 10, 20, 50, 100 AU/mL	6 Levels: 0, 3, 10, 30, 100, 300 U/mL
4.	Cut-off	8 AU/mL	8 AU/mL	15 AU/mL
5.	Incubation Times	45-30-15 minutes	45-30-15 minutes	GLIA-A and GLIA-G (REF 7501US and REF 7502US, respectively): 30-15-15 minutes GLIA-A and GLIA-G (REF 7501US and REF 7502US, respectively): 30-30-30 minutes
6.	Sample Diluent	Ready-to-use	Ready-to-use	5X concentrate
7.	Wash Solution/ Buffer	20X concentrated	20X concentrated	50X concentrated
8.	Linearity Range	1.1 – 100 AU/mL	1.1 – 100 AU/mL	7.4 – 102.5 U/mL
9.	Claimed Limit of Detection	1.1 AU/mL	1.1 AU/mL	1.0 U/mL

Table 3 Device Similarities Between α-Gliatest® IgG, α-GliaPep® IgG and Predicate (Aeskulisa® Glia A, K052439

No.	Item	α-Gliatest® IgG	α-GliaPep® IgG	Predicate AESKULISA® Glia-G (K052439)
1.	Intended Use	The α-Gliatest® IgG is intended for the semi-quantitative determination of IgG antibodies directed against gliadin in human serum. The assay is an aid in the diagnosis of celiac disease and should be used in conjunction with other serological tests and clinical findings.	The α-GliaPep® IgG is intended for the semi-quantitative determination of IgG antibodies directed against deamidated gliadin peptide in human serum. The assay is an aid in the diagnosis of celiac disease and should be used in conjunction with other serological tests and clinical findings.	The AESKULISA® Glia-G is a solid phase enzyme immunoassay for the semi-quantitative and qualitative detection of IgG antibodies against gliadin in human serum. The assay is an aid in the diagnosis of celiac disease (gluten-sensitive enteropathy) and should be used in conjunction with other serological tests and clinical findings.
2.	Methodology	ELISA	Same	Same
3.	Analyte	IgG antibodies against gliadin in human serum	IgG antibodies against deamidated gliadin peptide in human serum	IgA antibodies against gliadin in human serum

No.	Item	α-Gliatest® IgG	α-GliaPep® IgG	Predicate AESKULISA® Glia-G (K052439)
4.	Enzyme-Conjugate	Horseradish peroxidase	Same	Same
5.	Substrate/ Chromogen	TMB	Same	Same
6.	OD Reading	450 nm	Same	Same
7.	Positive Control	Human serum	Same	Same
8.	Negative Control	Human serum	Same	Same
9.	Storage	2-8°C	Same	Same
10.	Patient Sample Dilution	1:101	Same	Same
11.	Patient Sample Volume Required	100 µL	Same	Same

Table 4 Device Differences Between α-Gliatest® IgG, α-GliaPep® IgG and Predicate (Aeskulisa® Glia A, K052439)

No.	Item	α-Gliatest® IgG	α-GliaPep® IgG	Predicate AESKULISA® Glia-G (K052439)
1.	Capture Antigen	Purified α-gliadin antigen	Deamidated gliadin peptide	Purified α-gliadin antigen
2.	Controls	Positive, Negative Controls	Positive, Negative Controls	Positive, Negative, and Cut-off Controls
3.	Calibrators	5 Levels: 2, 10, 20, 50, 100 AU/mL	5 Levels: 0, 10, 20, 50, 100 AU/mL	6 Levels: 0, 3, 10, 30, 100, 300 U/mL
4.	Cut-off	50 Au/mL	10 AU/mL	15 AU/mL
5.	Incubation Times	45-30-15 minutes	45-30-15 minutes	Glia-A and Glia-G (REF 7501US and REF 7502US, respectively): 30-15-15 minutes Glia-A and GLIA-G (REF 7501US and REF 7502US, respectively): 30-30-30 minutes
6.	Sample Diluent	Ready-to-use	Ready-to-use	5X concentrated
7.	Wash Solution/ Buffer	20X concentrated	20X concentrated	50X concentrated
8.	Linearity Range	2.5 - 99.4 AU/mL	1.1 - 100 AU/mL	12.4 – 117.6 U/mL
9.	Claimed Limit of Detection	2.4 AU/mL	1.1 AU/mL	1.0 U/mL

10. Standard/Guidance Document Referenced

The following standards were referenced in the submission:

- CLSI EP5-A2, "Evaluation of Precision Performance of Quantitative Measurement Methods"
- CLSI EP6-A, "Evaluation of the Linearity of Quantitative Measurement Procedures; A Statistical Approach"
- CLSI EP7-A2, "Interference Testing in Clinical Chemistry"
- CLSI EP17-A, "Protocols for Determination of Limits of Detection and Limits of Quantitation"
- CLSI C28-A2, "How to Define and Determine Reference Intervals in the Clinical Laboratory"
- CLSI EP9-A2, "Method Comparison and Bias Estimation Using Patient Samples"

11. Performance Characteristics

11.1 Analytical Performance

11.1.1 Precision Study

The intra-assay precision studies were each performed in one (1) assay run. Results are summarized in Tables 5 - 8.

Table 5 Intra-assay Precision Results for α-Gliatest® IgA

Sample No.	1	2	3	4	5	6	7	8
Mean (AU/mL)	98.0	73.7	68.7	17.9	8.8	3.0	3.0	1.9
SD	3.50	2.62	2.08	0.49	0.30	0.20	0.08	0.15
CV%	3.6	3.6	3.0	2.7	3.5	6.8	2.7	7.7

Table 6 Intra-assay Precision Results for α-Gliatest® IgG

Sample No.	1	2	3	4	5	6	7	8
Mean (AU/mL)	99.6	80.4	75.0	61.9	60.6	24.3	10.0	5.1
SD	2.38	3.35	2.53	2.35	2.39	0.86	0.36	0.28
CV%	2.4	4.2	3.4	3.8	3.9	3.6	3.6	5.4

Table 7 Intra-assay Precision Results for α-GliaPep® IgA

Sample No.	1	2	3	4	5	6	7	8
Mean (AU/mL)	98.2	86.6	65.8	17.8	9.7	4.4	2.7	1.8
SD	6.61	2.83	4.43	0.95	0.94	0.25	0.19	0.15
CV%	6.7	3.3	6.7	5.3	9.8	5.7	7.0	8.6

Table 8 Intra-assay Precision Results for α-GliaPep® IgG

Sample No.	1	2	3	4	5	6	7	8
Mean (AU/mL)	97.5	55.6	24.5	15.1	10.4	8.1	6.2	4.0
SD	5.69	2.73	1.29	0.95	0.62	0.30	0.44	0.19
CV%	5.8	4.9	5.3	6.3	5.9	3.6	7.1	4.7

The inter-run (between days) precision study results are summarized in Tables 9 -12.

Table 9 Inter-run Precision Results for α-Gliatest® IgA

Sample No.	1	2	3	4	5	6	7	8
Mean (AU/mL)	95.9	77.8	69.0	17.8	9.0	3.3	3.1	1.9
SD	3.15	7.68	3.94	0.82	1.30	0.24	0.26	0.33
CV%	3.3	9.9	5.7	4.6	14.4	7.2	8.3	17.3

Table 10 Inter-run Precision Results for α-Gliatest® IgG

Sample No.	1	2	3	4	5	6	7	8
Mean (AU/mL)	97.9	82.4	75.5	64.4	60.2	26.1	10.6	5.8
SD	1.53	2.48	2.62	2.12	4.73	2.76	0.46	0.99
CV%	1.6	3.0	3.5	3.3	7.9	11.0	4.3	16.9

Table 11 Inter-run Precision Results for α-GliaPep® IgA

Sample No.	1	2	3	4	5	6	7	8
Mean (AU/mL)	96.6	84.4	61.1	18.1	9.6	3.8	2.8	1.5
SD	2.19	4.97	4.50	2.24	0.81	0.54	0.20	0.22
CV%	2.3	5.9	7.4	12.4	8.4	14.2	7.2	14.9

Table 12 Inter-run Precision Results for α-GliaPep® IgG

Sample No.	1	2	3	4	5	6	7	8
Mean (AU/mL)	97.5	49.3	25.4	15.9	10.0	7.9	5.9	4.1
SD	2.17	4.39	2.44	1.30	0.81	0.33	0.29	0.39
CV%	2.2	8.9	9.6	8.2	8.1	4.2	4.9	9.4

The inter-lot precision study results are summarized in Tables 13-16.

Table 13 Inter-lot Precision Results for α-Gliatest® IgA

Serum Sample No.	1	2	3	4	5
Mean (AU/mL)	87.3	42.8	22.7	11.6	7.1
S.D.	0.81	2.46	1.22	1.18	0.28
C.V. (%)	0.9	5.8	5.4	10.1	3.9

Table 14 Inter-lot Precision Results for α-Gliatest® IgG

Serum Sample No.	1	2	3	4	5
Mean (AU/mL)	84.9	50.3	42.7	24.4	11.1
S.D.	2.13	1.07	0.72	1.01	0.15
C.V. (%)	2.5	2.1	1.7	4.1	1.4

Table 15 Inter-lot Precision Results for α-GliaPep® IgA

Serum Sample No.	1	2	3	4	5
Mean (AU/mL)	85.4	42.6	22.6	14.3	7.3
S.D.	1.79	1.86	1.83	0.50	0.38
C.V. (%)	2.1	4.4	8.1	3.5	5.1

Table 16 Inter-lot Precision Results for α-GliaPep® IgG

Serum Sample No.	1	2	3	4	5
Mean (AU/mL)	83.1	45.6	26.3	13.1	4.1
S.D.	0.99	1.31	0.39	1.34	0.12
C.V. (%)	1.2	2.9	1.5	10.2	3.0

11.1.2 Linearity/Assay Reportable Range

Linearity was studied using four (4) positive serum samples each for the α-Gliatest® IgA, α-Gliatest® IgG, α-GliaPep® IgA, and α-GliaPep® IgG. Each sample was diluted with a low concentration serum sample at around the limit of detection (LoD), 1.1 AU/mL for α-Gliatest® IgA, 2.4 AU/mL for α-Gliatest® IgG, 1.1 AU/mL for α-GliaPep® IgA , and 1.1 AU/mL for α-GliaPep® IgG, respectively, using a dilution scheme.

The results of one (1) representative sample for α-Gliatest® IgA show a slope of 1.017 (95% C.I. 0.991 to 1.044), Y-intercept of -1.637 (95% C.I. -3.210 to -0.064) and R^2 of 0.9988. The results of one (1) representative sample for α-Gliatest® IgG show a slope of 0.997 (95% C.I. 0.931 to 1.064), Y-intercept of 1.857 (95% C.I. -2.182 to 5.896) and R^2 of 0.9924. The results of one (1) representative sample for α-GliaPep® IgA show a slope of 1.018 (95% C.I. 0.994 to 1.042), Y-intercept of -1.697 (95% C.I. -3.075 to 0.320) and R^2 of 0.9990. The results of one (1) representative sample for α-Gliatest® IgG show a slope of 1.014 (95% C.I. 0.987 to 1.041), Y-intercept of -1.705 (95% C.I. -3.354 to -0.056) and R^2 of 0.9988.

The results of the study support the linear range and the claimed assay range of 1.1-100 AU/mL for α-Gliatest® IgA, 2.5-99.4 AU/mL for α-Gliatest® IgG, 1.1-100 AU/mL for α-GliaPep® IgA, and 1.1-100 AU/mL for α-GliaPep® IgG.

11.1.3 Traceability, Stability and Expected Values (Controls and Calibrators)

- **Traceability**

  Calibrators are not traceable to any recognized standards. Calibrators are dilutions of pooled sera with anti-gliadin antibody from patients with celiac disease. The new calibrator and control lots are formulated from an array of anti-gliadin antibody positive sera obtained from various commercial plasma centers stored at -70°C. The calibrators and controls are taken from different pooled sera. As new lots of calibrators are developed, studies are performed to calibrate values against original calibrators. Each lot of calibrator is also tested in comparison with normal human sera, clinical samples and internal standards. The concentration values of the calibrators are as follows:

Calibrator	α-Gliatest® IgA	α-Gliatest® IgG
Cal S5	100 AU/mL	100 AU/mL
Cal S4	50 AU/mL	50 AU/mL
Cal S3	20 AU/mL	20 AU/mL
Cal S2	10 AU/mL	10 AU/mL
Cal S1	0 AU/mL	2 AU/mL

Calibrator	α-GliaPep® IgA	α-GliaPep® IgG
Cal S5	100 AU/mL	100 AU/mL
Cal S4	50 AU/mL	50 AU/mL
Cal S3	20 AU/mL	20 AU/mL
Cal S2	10 AU/mL	10 AU/mL
Cal S1	0 AU/mL	0 AU/mL

- **Kit Stability**

  Stability studies support the expiration date claims of 12 months at 2-8°C for the α-Gliatest® IgA, α-Gliatest® IgG, α -GliaPep® IgA, and α-GliaPep® IgG.

- **Sample Stability**
  Specimens should be stored at 2-8°C for no longer than five (5) days. For longer storage, serum specimens should be frozen at -20°C. Repeated freezing and thawing of samples should be avoided.

11.1.4 Detection Limit

The limits of blank (LoB) and the claimed limits of detection (LoD) for α-Gliatest® IgA, α-Gliatest® IgG, α-GliaPep® IgA and α-GliaPep® IgG, are shown in Table 17.

Table 17 Limits of Blank and Claimed Limits of Detection for α-Gliatest® IgA & IgG and α-GliaPep® IgA & IgG

	LoB (AU/mL)	Claimed LoD (AU/mL)
α-Gliatest® IgA	0.59	1.1
α-Gliatest® IgG	1.66	2.4
α-GliaPep® IgA	0.13	1.1
α-GliaPep® IgG	0.18	1.1

11.1.5 Analytical Specificity

Cross-reactivity studies were performed for α-Gliatest® IgA, α-Gliatest® IgG, α-GliaPep® IgA, and α-GliaPep® IgG, using 148 characterized clinical samples from individuals with autoimmune disorders, such as Hashimoto's Thyroiditis (HT), Graves' Disease (GD), Systemic Lupus Erythematosus (SLE), Rheumatoid Arthritis (RA), Sjogren's, Systemic Sclerosis and Autoimmune Hepatitis (AH); patients with Inflammatory Bowel Disease (IBD), including Crohn's Disease and Ulcerative Colitis (UC); Irritable Bowel Syndrome (IBS), Type 1 Diabetes and *H. pylori* infection.

One (1) RA, 11 SLE, seven (7) HT, six (6) GD, one (1) AH, one (1) Crohn's Disease, five (5) IBS, and four (4) Type 1 Diabetes out of 148 samples (36/148, 24.3%) were tested positive for α-Gliatest IgA.
One (1) RA, two (2) SLE, one (1) GD, one (1) Sjogren's, two (2) Crohn's Disease, two (2) UC, five (5) IBS, and three (3) Type 1 Diabetes out of 148 samples (17/148, 11.5%) were tested positive for α-Gliatest IgG.

Four (4) HT, one (1) GD, one (1) AH, two (2) IBS, one (1) Type 1 Diabetes, and one (1) *H. pylori* out of 148 samples (10/148, 6.8%) were

tested positive for α-GliaPep IgA. Two (2) RA, two (2) SLE, three (3) HT, four (4) GD, one (1) AH, two (2) Crohn's Disease, one (1) UC, two (2) IBS, two (2) Type 1 Diabetes, and three (3) *H. pylori* out of 148 samples (22/148, 14.9%) were tested positive for α-GliaPep IgG.

Interference was studied by mixing the serum samples with known anti-gliadin antibody levels with the potentially interfering substances.

- The study results demonstrated that hemoglobin (up to 2 g/L), bilirubin (up to 342 µmol/L), rheumatoid factor (up to 100 IU/mL) or lipids (triglycerides up to 1.08 mmol/L) does not significantly interfere with the performance of the α-Gliatest IgA.

- The study results demonstrated that hemoglobin (up to 2 g/L), bilirubin (up to 256 µmol/L), rheumatoid factor (up to 100 IU/mL) or lipids (triglycerides up to 1.08 mmol/L) does not significantly interfere with the performance of the α-Gliatest IgG.

- The study results demonstrated that hemoglobin (up to 1.5 g/L), bilirubin (up to 256 µmol/L), rheumatoid factor (up to 100 IU/mL) or lipids (triglycerides up to 1.08 mmol/L) does not significantly interfere with the performance of the α-GliaPep IgA.

- The study results demonstrated that hemoglobin (up to 1.5 g/L), bilirubin (up to 342 µmol/L), rheumatoid factor (up to 100 IU/mL) or lipids (triglycerides up to 1.47 mmol/L) does not significantly interfere with the performance of the α-GliaPep IgG.

11.1.6 Assay Cut-off

The normal range of each assay was established by testing over 160 serum samples from healthy subjects and non-celiac controls, such as Inflammatory Bowel Disease (IBD) patients, on each assay.

The assay cut-off value for α-Gliatest® IgA was determined as follows:

<8 AU/mL	Negative
≥8 AU/mL	Positive

The assay cut-off value for α-Gliatest® IgG was determined as follows:

<50 AU/mL Negative

≥50 AU/mL Positive

The assay cut-off value for α-GliaPep® IgA was determined as follows:

<8 AU/mL Negative

≥8 AU/mL Positive

The assay cut-off value for α-GliaPep® IgG was determined as follows:

<10 AU/mL Negative

≥10 AU/mL Positive

11.2 Method Comparison Studies

11.2.1 α-Gliatest® IgA

A method comparison study was performed which compared the α-Gliatest® IgA to a comparator test using 178 clinical samples. These samples consist of clinically-diagnosed celiac positive (clinical history and/or biospy) and negative samples. The negative samples were obtained from healthy blood donors, inflammatory bowel disease (IBD) patients, irritable bowel syndrome (IBS) patients, patients affected by food intolerances, patients with autoimmune disorders, patients with infectious diseases and patients with Type 1 diabetes. All samples were tested using α-Gliatest® IgA and the comparator test kit. The results of the studies are summarized in Table 18.

Table 18 Results of Method Comparison Study for α-Gliatest® IgA

		Aeskulisa Glia A (K052439) (Cut-off = 15 AU/mL)		
		Positive	**Negative**	**Total**
α-Gliatest® IgA (Cut-off 8 AU/mL)	**Positive**	52	18	**70**
	Negative	6	102	**108**
	Total	**58**	**120**	**178**

Positive Agreement = 89.7% (95% C.I. 78.8% - 96.1%)
Negative Agreement = 85.0% (95% C.I. 77.3% - 90.9%)
Overall Agreement = 86.5% (95% C.I. 80.6% - 91.2%)

C.I. = Confidence Interval

11.2.2 α-Gliatest® IgG

A method comparison study was performed which compared the α-Gliatest® IgG to a comparator test using 198 clinical samples. These samples consist of 51 clinically-diagnosed celiac positive (clinical history and/or biospy), which include 10 total IgA-deficient celiac patients, and negative samples. The negative samples were obtained from healthy blood donors, inflammatory bowel disease (IBD) patients, irritable bowel syndrome (IBS) patients, patients affected by food intolerances, patients with autoimmune disorders, patients with infectious diseases and patients with Type 1 diabetes. All samples were tested using the α-Gliatest® IgG and the comparator test kit. The results of the studies are summarized in Table 19.

Table 19 Results of Method Comparison Study for α-Gliatest® IgG

		Aeskulisa® Glia G (K052439) (Cut-off = 15 AU/mL)		
		Positive	**Negative**	**Total**
α-Gliatest® IgG (Cut-off 50 AU/mL)	**Positive**	52	15	**67**
	Negative	14	117	**131**
	Total	**66**	**132**	**198**

Positive Agreement = 78.8% (95% C.I. 67.0% - 87.9%)
Negative Agreement = 88.6 % (95% C.I. 82.0% - 93.5%)
Overall Agreement = 85.4% (95% C.I. 79.6% - 90.0%)

11.2.3 α-GliaPep® IgA

A method comparison study was performed which compared the α-GliaPep® IgA to a comparator test using 179 clinical samples within the linearity range of the assay. These samples consist of clinically-diagnosed celiac positive (clinical history and/or biospy) and negative samples. The negative samples were obtained from healthy blood donors, IBD patients, IBS patients, patients affected by food intolerances, patients with autoimmune disorders, patients with infectious diseases and patients with Type 1 diabetes. All samples were tested using α-GliaPep® IgA and the comparator test kit. The results of the studies are summarized in Table 20.

Table 20 Results of Method Comparison Study for α-GliaPep® IgA

		Aeskulisa® Glia A (K052439) (Cut-off = 15 AU/mL)		
		Positive	**Negative**	**Total**
α-GliaPep® IgA (Cut-off 8 AU/mL)	**Positive**	36	11	**47**
	Negative	14	118	**132**
	Total	**50**	**129**	**179**

Positive % Agreement = 72.0% (95% C.I. 57.5% - 83.8%)
Negative % Agreement = 91.5% (95% C.I. 85.3% - 95.7%)
Overall % Agreement = 86.0% (95% C.I. 80.1% - 90.8%)

11.2.4 α-GliaPep® IgG

The α-GliaPep® IgG test was tested in comparison to the predicate, using 201 clinical samples within the linearity range of the assay. These samples consist of 57 clinically-diagnosed celiac positive (clinical history and/or biospy), which include 10 total IgA-deficient celiac patients, and 146 negative samples. The negative samples were ontained from healthy blood donors, IBD patients, IBS patients, patients affected by food intolerances, patients with autoimmune disorders, patients with infectious diseases and patients with Type 1 diabetes. All samples were tested using the α-GliaPep® IgG and the comparator test kit. The results of the studies are summarized in Table 21.

Table 21 Results of Method Comparison Study for α-GliaPep® IgG

		Aeskulisa® Glia G (K052439) (Cut-off = 15 AU/mL)		
		Positive	**Negative**	**Total**
α-GliaPep® IgG (Cut-off 10 AU/mL)	**Positive**	50	16	**66**
	Negative	13	122	**135**
	Total	**63**	**138**	**201**

Positive % Agreement = 79.4% (95% C.I. 67.3% - 88.5%)
Negative % Agreement = 88.4% (95% C.I. 81.9% - 93.2%)
Overall % Agreement = 85.6% (95% C.I. 79.9% - 90.1%)

11.3 Clinical Studies

11.3.1 α-Gliatest® IgA

For the α-Gliatest® IgA, the clinical study included 262 clinical samples, of which 114 are positive celiac patients and 148 are negative samples from disease control patients with autoimmune disorders, infectious diseases, IBD, IBS and Type 1 diabetes. The celiac patient samples were diagnosed with clinical findings and/or confirmed with biopsy. Table 22 demonstrates the clincal performance of the α-Gliatest® IgA.

Table 22 Clinical Study Results of α-Gliatest® IgA

		Celiac Disease		
		Positive	**Negative**	**Total**
α-Gliatest® IgA (Cut-off 8 AU/mL)	**Positive**	79	36	**115**
	Negative	35	112	**147**
	Total	**114**	**148**	**262**

Sensitivity = 69.3% (95% C.I. 60.0% - 77.6%)
Specificity = 75.7% (95% C.I. 67.9% - 82.3%)

For the α-Gliatest IgA assay, 196 healthy blood donor samples were also tested, of which six samples (3.1%) tested positive.

11.3.2 α-Gliatest® IgG

For the α-Gliatest® IgG, the clinical study included 285 clinical samples, of which 127 are positive celiac patients, 10 are total IgA-deficient celiac patients and 148 are negative samples from disease control patients with autoimmune disorders, infectious diseases, IBD, IBS and Type 1 diabetes. The positive celiac patient samples were diagnosed with clinical findings and confirmed with biopsy. Table 23 demonstrates the clinical performance of the α-Gliatest® IgG assay.

Table 23 Clinical Study Results of α-Gliatest® IgG

		Celiac Disease		
		Positive	**Negative**	**Total**
α-Gliatest® IgG (Cut-off 50 AU/mL)	**Positive**	109	17	**126**
	Negative	28	131	**159**
	Total	**137**	**148**	**285**

Sensitivity = 79.6% (95% C.I. 71.8% - 86.0%)
Specificity = 88.5% (95% C.I. 82.2% - 93.2%)

For the α-Gliatest IgG assay, 196 healthy blood donor samples were also tested, of which 10 samples (5.1%) tested positive.

11.3.3 α-GliaPep® IgA

For the α-GliaPep® IgA, the clinical study included 241 clinical samples, of which 93 are positive celiac patients and 148 are negative samples from disease control patients with autoimmune disorders, infectious diseases, IBD, IBS and Type 1 diabetes. The celiac patient samples were diagnosed with clinical findings and confirmed with biopsy. Table 24 demonstrates the clincal performance of the α-GliaPep® IgA.

Table 24 Clinical Study Results of α-GliaPep® IgA

		Celiac Disease		
		Positive	**Negative**	**Total**
α-Gliapep® IgA (Cut-off 8 AU/mL)	**Positive**	74	10	**84**
	Negative	19	138	**157**
	Total	**93**	**148**	**241**

Sensitivity = 79.6% (95% C.I. 69.9% - 87.2%)
Specificity = 93.2% (95% C.I. 87.9% - 96.7%)

For the α-GliaPep IgA assay, 145 healthy blood donor samples were also tested, of which five samples (3.5%) tested positive.

11.3.4 α-GliaPep® IgG

For the α-GliaPep® IgG, the clinical study included 253 clinical samples, of which 95 are positive celiac patients, 10 are total IgA-deficient celiac patients and 148 are negative samples from disease control patients with autoimmune disorders, infectious diseases, IBD, IBS and Type 1 diabetes patient samples. The positive celiac patient samples were diagnosed with clinical findings (31.6%) and confirmed with biopsy (68.4%). Table 25 demonstrates the clinical performance of the α-GliaPep® IgG assay.

Table 25 Clinical Study Results of α-GliaPep® IgG

		Celiac Disease		
		Positive	**Negative**	**Total**
α-Gliatest® IgG (Cut-off 50 AU/mL)	**Positive**	95	22	**117**
	Negative	10	126	**136**
	Total	**105**	**148**	**253**

Sensitivity = 90.5% (95% C.I. 83.2% - 95.3%)
Specificity = 85.1% (95% C.I. 78.4% - 90.4%)

For the α-GliaPep IgG assay, 145 healthy blood donor samples were also tested, of which 13 samples (9.0%) tested positive.

11.4 Expected Results

The expected result in the normal population is negative. However, the incidence of celiac disease in the normal population is about 1%. Some apparently healthy individuals may test positive for the anti-gliadin antibodies (AGA).

12 Conclusion

The submitted material in this 510(k) Premarket Notification is sufficient to support a substantial equivalence decision with the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Grifols USA, LLC
C/O Ms. Catherine L. Wong
Director, Regulatory Affairs
2410 Lillyvale Avenue
Los Angeles, CA 90032

DEC 1 4 2012

Re: k113377
Trade/Device Name: α-Gliatest® IgA, α-Gliatest® IgG, α-GliaPep® IgA, α-GliaPep® IgG
Regulation Number: 21 CFR §866.5750
Regulation Name: Radioallergosorbent (RAST) Immunological Test System
Regulatory Class: Class II
Product Code: MST
Dated: November 27, 2012
Received: November 28, 2012

Dear Ms. Wong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Reena Philip -S

for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Center for Devices and Radiological Health

1. Indication for Use Statement for α-Gliatest® IgA

510(k) Number (if known): K113377

Device Name: α-Gliatest® IgA

Indication for Use:

The α-Gliatest® IgA is intended for the semi-quantitative determination of IgA antibodies directed against gliadin in human serum. The assay is an aid in the diagnosis of celiac disease and should be used in conjunction with other serological tests and clinical findings.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

NZP Misar Pampoic

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113377

2. Indication for Use Statement for α-Gliatest® IgG

510(k) Number (if known): K113377

Device Name: α-Gliatest® IgG

Indication for Use:

The α-Gliatest® IgG is intended for the semi-quantitative determination of IgG antibodies directed against gliadin in human serum. The assay is an aid in the diagnosis of celiac disease and should be used in conjunction with other serological tests and clinical findings.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

NZP Nisar Pamposi

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113377

3. Indication for Use Statement for α-GliaPep® IgA

510(k) Number (if known): K113377

Device Name: α-GliaPep® IgA

Indication for Use:

The α-GliaPep® IgA is intended for the semi-quantitative determination of IgA antibodies directed against deamidated gliadin peptide in human serum. The assay is an aid in the diagnosis of celiac disease and should be used in conjunction with other serological tests and clinical findings.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Nazmisar Pampori

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113377

4. Indication for Use Statement for α-GliaPep® IgG

510(k) Number (if known): K113377

Device Name: α-GliaPep® IgG

Indication for Use:

The α-GliaPep® IgG is intended for the semi-quantitative determination of IgG antibodies directed against deamidated gliadin peptide in human serum. The assay is an aid in the diagnosis of celiac disease and should be used in conjunction with other serological tests and clinical findings.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

NZP Nisar Pamporic

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113377